Appl. No.: 10/614,408

Art Unit; 1615

Reply to Office Action of 08/09/2007

Patent 17571 (AP) (1957205-0020)

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

- 1.-21. (CANCELED)
- 22. (WITHDRAWN) A method of sterilizing a polymeric material for use in a body of a mammal comprising irradiating said polymeric material at a temperature below 25°C.
- 23. (WITHDRAWN) The method of claim 22 wherein the polymeric material further comprises a therapeutically active agent.
- 24. (WITHDRAWN) The method of claim 22 wherein said temperature is below about 15°C.
- 25. (WITHDRAWN) The method of claim 22 wherein said temperature is below about 10°C.
- 26. (WITHDRAWN) The method of claim 22 wherein said temperature is below about 5°C.
- 27.-69. (CANCELED)
- 70. (NEW) A gamma irradiated sterilized therapeutic composition comprising microparticles comprising at least one polymer and at least one therapeutically active agent wherein said microparticles are less aggregated when gamma irradiated at less than 5°C than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma irradiation at a temperature greater than 5°C.

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- 71. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said at least one polymer is poly(lactide-co-glycolide) (PLGA) or polylactic acid (PLA).
- 72. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 71 wherein said at least one polymer is PLGA.
- 73. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said at least one therapeutic agent is tazarotene.
- 74. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said dose of gamma irradiation is between 2.5 and 4.5 Mrad.
- 75. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said sterilized therapeutic composition is a freeze-dried powder.
- 76. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said microparticles are less aggregated when gamma irradiated at less than 5°C than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma irradiation at a temperature greater than 5°C.
- 77. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said therapeutic composition is a sustained delivery composition.
- 78. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 70 wherein said microparticles have an average size less than 100 micrometers in diameter.
- 79. (NEW) A gamma irradiated sterilized therapeutic composition comprising microparticles having an average size less than 100 micrometers in diameter comprising PLGA and one therapeutically active agent wherein said microparticles are less aggregated when gamma irradiated at less than 5°C than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma irradiation at a temperature greater than 5°C.

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- 80. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 79 wherein said at least one therapeutic agent is tazarotene.
- 81. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 79 wherein said dose of gamma irradiation is between 2.5 and 4.5 Mrad.
- 82. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 79 wherein said sterilized therapeutic composition is a freeze-dried powder.
- 83. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 79 wherein said therapeutic composition is a sustained delivery composition.
- 84. (NEW) A gamma irradiated sterilized therapeutic composition comprising microparticles comprising PLGA and tazarotene wherein said microparticles are less aggregated when gamma irradiated at less than 5°C than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma irradiation at a temperature greater than 5°C.
- 85. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 84 wherein said microparticles have an average size less than 100 micrometers in diameter.
- 86. (NEW) A gamma irradiated sterilized therapeutic composition comprising microparticles having an average size less than 100 micrometers comprising PLGA and tazarotene
- 87. (NEW) The gamma irradiated sterilized therapeutic composition according to claim 86 wherein said therapeutic composition is a sustained delivery composition.